

REMARKS

The Examiner's Office Action of March 11, 2005 has been received and carefully considered. Reconsideration of this application in light of the amendment and the allowance of this application are respectfully requested.

Prior to this amendment, claim 1 was pending in the application. By this amendment, claim 1 is amended and new claims 53-69 are added. Accordingly, upon entry of this amendment, claims 1, 53-69 are pending in the application and are believed to be in proper condition for allowance.

Initially, in the Office Action, the Examiner states that the listing of references in the specification is not a proper information disclosure statement and request a list of all patents, publications, or other information to be submitted for consideration by the Office under 37 CFR 1.98(b). In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, an Information Disclosure Statement conforming with 37 C.F.R. § 1.98 accompanies this Amendment.

The Examiner also objected to the specification stating that the specification contains typographical errors. In response, the paragraphs [0014], [0015], [0049] and [0060] have been amended herein to correct these informalities.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,635,488 to Kremer et al. The Examiner asserts that Kremer discloses a sampling device comprising a hollow tube having at least one open end, and a collecting nib secured in the open end of the tube and having an inner extremity facing the interior of the tube and an outer tip projecting beyond the last mentioned end of the tube for contact with a fluid to be collected. The Examiner further asserts that the device of Kremer is also provided with a cap for closing the open end of the tube and with an elongated, absorbent and rigid analysis element having an agent that undergoes an observable change upon contact with a substance to be detected in a body fluid sample. In this regard, the Examiner asserts that the analysis element has a proximal end mounted in the cap, such that when the cap is in position closing the open end of the tube, the analysis element extends through the tube and its distal end is in fluid transferring contact with the inner extremity of the nib to receive and absorb fluid collected by the nib. The Examiner also asserts that in one embodiment, the device having an analysis element, either in particulate form

or strip form, also comprises an absorbent but hydrophobic body situated between the nib and the analysis element to prevent premature transfer of samples to the analysis element. The Examiner further asserts that Kremer discloses that the nib absorbs and retains a fluid sample by wicking or capillary action and should be contacted with, for example, the tongue until the nib is completely saturated with body fluid since a given porous nib has an essentially fixed fluid capacity, saturation assures collection of a sample of predetermined volume. The Examiner asserts that the device also comprises a transparent sidewall for visual observation of the color change. The Applicants respectfully traverse this rejection for the reasons below.

With respect to the independent claims, Kremer does not disclose, teach, or otherwise suggest Applicants' invention as now claimed. For example, claim 1 is amended to recite an apparatus for collection and lateral flow chromatography of an oral fluid, comprising a capillary matrix having exposed a surface for receiving oral fluid, a lateral flow chromatography strip where the lateral flow chromatography strip is in communication with the capillary matrix, and a blocking strip coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains at least one blocking agent.

Kremer does not teach or suggest such a device. Kremer is directed to a body fluid sampling device comprising a hollow tube having at least one open end, and a collecting nib secured in that open end of the tube and having an inner extremity facing the interior of the tube and an outer tip projecting beyond the end of the tube for contact with a fluid to be collected. (Kremer, col. 2, ll. 50-55)

Regarding "the hydrophobic body to prevent premature transfer of sample to the packed column" asserted by the Examiner in the Office Action, Kremer discloses as follows:

"In the modification shown in FIGS. 9 and 12, the body 50 or 50a of FIGS. 8 and 11 is replaced with a solid porous body 52 or 52a similarly disposed at the distal end of the analysis element for fluid-transmitting contact with (but, again, preferably separable from) the nib and the body 52 or 52a is not water-wettable (Kremer, col. 10, ll. 15-20). For example, it may be made of the same hydrophobic plastic as the nib (e.g. polyethylene or polypropylene) without the wetting agent used in the nib (Kremer, col. 10, ll. 20-23). Consequently, even if

the cap 16' or 16" is in closed position and the body 52 or 52a is in contact with the nib, as shown, during collection of a body fluid sample by the nib, the sample cannot migrate beyond the nib to the strip 44 or column 46 because its ascent is blocked by the hydrophobic body 52 or 52a (Kremer, col. 10, ll. 23-29)."

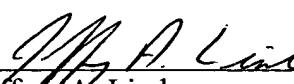
Applicants' blocking strip is coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains at least one blocking agent. Kremer does not teach or suggest such a blocking strip. Nor would the teachings of Kremer have rendered such a device obvious to one of ordinary skill in the art. In view of the above Amendments and remarks, Applicants respectfully request that the Examiner's rejection based on Kremer be withdrawn.

Finally, the new claims 53-66, 68 and 69 have been added are all dependent claims, each of which ultimately depend on independent claim 1 which is believed to be allowable. Correspondingly, the entry and the allowance of these new claims are also respectfully requested. The newly added claim 67 recites limitations found in independent claim 1 and dependent claims. In this regard, no new matter has been added by the above amendments to the claims.

For the foregoing reasons, Applicant believes that the application now in condition for allowance and a notice to that effect is respectfully requested. However, if the Examiner deems that any issue remains after considering this response, he is invited to call the undersigned to expedite the prosecution and work out any such issue by telephone.

Respectfully submitted,

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